

APPENDIX B: CLEAN COPY OF PENDING CLAIMS

1. A submicron-reconstitute preliposome-lyophilate comprising a non-lipid surfactant.

3. The submicron-reconstitute preliposome-lyophilate of claim 1 wherein said surfactant is anionic, cationic or nonionic.

4. The submicron-reconstitute preliposome-lyophilate of claim 3 wherein said surfactant is nonionic.

5. The submicron-reconstitute preliposome-lyophilate of claim 4 wherein said surfactant is a Tween surfactant.

6. The submicron-reconstitute preliposome-lyophilate of claim 5 wherein said surfactant is Tween 20.

7. The submicron-reconstitute preliposome-lyophilate of claim 6 wherein said surfactant comprises from about 4 mole % to about 2 mole % of the lipid content of the submicron-reconstitute preliposome-lyophilate.

8. The submicron-reconstitute preliposome-lyophilate of claim 3 wherein said surfactant comprises from about 5 mole % to about 0.1 mole % of the lipid content of the submicron-reconstitute preliposome-lyophilate.

9. The submicron-reconstitute preliposome-lyophilate of claim 8 wherein said surfactant comprises from about 4 mole % to about 2 mole % of the lipid content of the submicron-reconstitute preliposome-lyophilate.

52. The submicron-reconstitute preliposome-lyophilate of claim 1, said preliposome-lyophilate being halogenated solvent-free.

53. A preliposome-lyophilate comprising a non-lipid surfactant and capable of forming liposomes having an average diameter of less than 400 nm when reconstituted in aqueous solution.

54. The preliposome-lyophilate of claim 53 wherein said surfactant is nonionic.

55. The preliposome-lyophilate of claim 54 wherein said nonionic surfactant is selected from the group consisting of polyoxyethylene sorbitan monolaurate having a molecular weight of approximately 1300 and polyoxyethylene sorbitan monooleate having a molecular weight of approximately 1350.

56. A non-aqueous material comprising a non-lipid surfactant and capable of forming liposomes upon addition of aqueous solution, wherein said liposomes have an average diameter of less than 400 nm.

57. A submicron-reconstitute preliposome-lyophilate product produced by a process comprising:

- (a) preparing a solution comprising at least one lipid dissolved in an aqueous/t-butanol solvent system and a non-lipid surfactant, wherein said solution does not contain liposomes at the time of lyophilization; and
- (b) lyophilizing said solution to form a submicron-reconstitute preliposome-lyophilate.

58. The product of claim 57 wherein said surfactant is anionic, cationic or nonionic.

59. The product of claim 58 wherein said surfactant is nonionic.

60. The product of claim 59 wherein said surfactant is a Tween surfactant.
61. The product of claim 60 wherein said surfactant is Tween 20.
62. The product of claim 60 wherein said surfactant is Tween 80.
63. The product of claim 61 or claim 62 wherein said surfactant comprises from about 4 mole % to about 2 mole % of the lipid content of the lyophilate.
64. The product of claim 58 wherein said surfactant comprises from about 5 mole % to about 0.1 mole % of the lipid content of the lyophilate.
65. The product of claim 64 wherein said surfactant comprises from about 4 mole % to about 2 mole % of the lipid content of the lyophilate.
66. A lyophilate comprising at least one lipid and a non-lipid surfactant of about 4 mole % or less of lipid content, wherein the lyophilate is capable of forming liposomes in about one minute with hand-shaking upon addition of aqueous solution, which liposomes have an average diameter of less than 400 nm.
67. The lyophilate of claim 66 further comprising a bioactive agent.
68. The lyophilate of claim 66 wherein said surfactant is nonionic.
69. The lyophilate of claim 68 wherein said surfactant is a Tween surfactant.
70. The lyophilate of claim 69 wherein said surfactant is Tween 20.
71. The lyophilate of claim 69 wherein said surfactant is Tween 80.

72. The lyophilate of claim 67 wherein the bioactive agent is selected from the group consisting of an antifungal agent, an antineoplastic agent, an antibiotic, an adjuvant, a vaccine, a contrast agent, a diagnostic agent, a drug targeting agent and a genetic fragment.

73. The lyophilate of claim 72 wherein the bioactive agent is an antifungal agent.

74. The lyophilate of claim 72 wherein the bioactive agent is an antineoplastic agent.

75. The lyophilate of claim 72 wherein the bioactive agent is an antibiotic.

76. The lyophilate of claim 72 wherein the bioactive agent is an adjuvant.

77. The lyophilate of claim 72 wherein the bioactive agent is a vaccine.

78. The lyophilate of claim 72 wherein the bioactive agent is a contrast agent.

79. The lyophilate of claim 72 wherein the bioactive agent is a diagnostic agent.

80. The lyophilate of claim 72 wherein the bioactive agent is a drug targeting agent.

81. The lyophilate of claim 72 wherein the bioactive agent is a genetic fragment.